Remarks

Introduction

The above-identified application has been carefully reviewed in light of the Office Action mailed September 21, 2004, which included a final rejection of the pending claims. This Amendment is being submitted with a Request for Continued Examination and a Petition for a Two-Month Extension of Time.

Claims 1-16 were pending. By way of this response, claims 1, 7, 8, and 16 have been amended, and claims 17-19 have been added. Support for the amendments and the new claims can be found in the specification as filed, and care has been taken to avoid adding new matter. Accordingly, claims 1-19 are currently pending.

Rejections Based On Estoppel Under 37 CFR 1.658(c)

Claims 1-16 remain rejected on the grounds of estoppel under 37 CFR 1.658(c).

Applicant disagrees with the rejection and reserves the right to traverse the rejection in the future at applicant's discretion. However, to advance the prosecution of the above-identified application, applicant has amended the claims, as set forth above. Applicant traverses this rejection as it relates to the present claims.

Applicant submits that the present claims, including claims 1-16, could not have been a basis of an additional count in the interference as proposed in the Office Action. For example,

Sanders does not disclose, teach, or even suggest treatment of a mucus secretion by administering a botulinum toxin at a location inferior to the nose of a patient, as recited in the present claims. In that regard, applicant submits that Sanders' teaching of transtympanic injection of a botulinum toxin to treat otitis media is at a location superior to the nose of a patient. The present claims have been amended to recite that the botulinum toxin is administered to a patient to treat a mucus secretion, which is not a rhinorrhea mucus secretion, by administering a botulinum toxin at a location that is inferior to the nose of the patient.

Applicant submits that the subject matter of the present claims could not have been presented during the interference. Applicant submits that the present claims are not identical with claim 5 of Sanders and are not obvious variants of claim 5 of Sanders. For example, the present claims recite administration of a botulinum toxin at a location inferior to the nose of a patient (which does not include the ear), and therefore, does not refer to transtympanic injection, as disclosed and claimed by Sanders. Thus, the subject matters of claim 5 of Sanders and the present claims are distinct and different, one from the other. For example, the present claims and the claims of Sanders, including claim 5, are directed to administration of a botulinum toxin at anatomically and physiologically different and distinct locations. Put another way, claim 5 of Sanders does not even suggest the present claims, including claims 1 to 16.

In view of the above, applicant submits that none of the present claims, and claims 1 to 16 in particular, could have

been properly added to the interference. Therefore applicant submits that the estoppel rejection under 37 CFR 1.658(c) has been overcome, and respectfully requests withdrawal of the rejection.

Rejections Under 35 U.S.C. § 102

Claims 1-16 remain rejected under 35 U.S.C. § 102(g) as allegedly being anticipated by Sanders. Claims 1-16 also remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Sanders and TOS (HNO).

Applicant respectfully traverses the rejections as they relate to the present claims.

Applicant maintains its position regarding the deficiencies of Sanders, or the combination of Sanders and TOS, regarding administration of a botulinum toxin to reduce a mucus secretion, as set forth in applicant's previous response.

In addition, applicant submits that neither Sanders nor TOS discloses, teaches, or even suggests administering a botulinum toxin, such as a botulinum toxin type A, to a patient to reduce a mucus secretion, which is not a symptom of rhinorrhea, and at a location inferior to the nose of the patient, as recited in claims 1 to 7. Furthermore, neither of the references discloses, teaches, or even suggests administering a botulinum toxin to a mucus secreting gland to treat a mucus secretion that is not a symptom of rhinorrhea and at a location inferior to the nose of the patient, as recited in claims 8 to 15. Similarly, the references do not disclose, teach, or even suggest injecting

an excessively secreting, cholinergic nervous system influenced gland or local mucus gland area of a human patient with a botulinum toxin type A to reduce an excessive mucus gland secretion that is not a symptom of rhinorrhea and at a location inferior to the nose of the patient, as recited in claim 16.

Sanders mentions that botulinum toxin may be used to treat otitis media by transtympanic injection (column 2, lines 39-40; column 10, lines 41-42; and column 12, lines 3-5). Such treatment requires injection of a botulinum toxin at a location superior to the nose of the patient. Thus, Sanders discloses treatment of rhinorrhea secretions and otitis media by administration of a botulinum toxin at a location superior to the nose of the patient.

In direct contrast, the present claims recite treatment of non-rhinorrhea mucus secretions by administration of a botulinum toxin at a location inferior to a patient's nose. The disclosure of Sanders for a treatment for otitis media by transtympanically administering botulinum toxin to a patient does not disclose, teach, or even suggest that the administration of a botulinum toxin reduced mucus secretions associated with otitis media.

In view of the above, applicant submits that the present claims, and claims 1-16 in particular, are not anticipated by Sanders under 35 U.S.C. § 102(g), or by Sanders and TOS under 35 U.S.C. § 102(b).

In addition, applicant submits that the present claims are unobvious from and patentable over Sanders, or the combination

of Sanders and TOS, under 35 U.S.C. § 103. For example, Sanders only discloses administration of a botulinum toxin to treat a mucus secretion by administration to a location superior to a patient's nose. As discussed in the specification at page 11, lines 22-33 of the above-identified application, the present claims exclude administration of a botulinum toxin near the nasal mucosa because the administration of the botulinum toxin may result in systemic delivery of the toxin due to the highly vascular nature of the nasal mucosa, and because conditions involving mucus secretions such as rhinorrhea and otitis media have a short duration compared to the effects provided by administration of the botulinum toxin. As understood by persons of ordinary skill in the art, the nasal mucosa and the mucosa of the middle ear are derived from the same types of tissue. Administration of a botulinum toxin at a location inferior to the nose of a patient indicates that the botulinum toxin is administered at a different and distinct target tissue. Thus, applicant submits that Sanders' disclosure of administration of a botulinum toxin to treat rhinorrhea and otitis media, which are treated by administration of a botulinum toxin at a location superior to the nose of the patient, and which have symptoms on the order of days instead of months, actually **teaches away** from the present claims.

In view of the above, applicant submits that the present claims, and claims 1-16 in particular, are unobvious from and patentable over Sanders, TOS, or any combination thereof, under 35 U.S.C. § 103.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of

the prior art disclose, teach, or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. For example, the prior art does not disclose administration of a botulinum toxin to reduce a mucus secretion that is a non-rhinorrhea mucus secretion at a region such as the gastrointestinal tract, the genital tract, or the respiratory tract at a location inferior to the nose of the patient, as recited in claims 17 and 18. In addition, the prior art does not disclose administration of a botulinum toxin to reduce a mucus secretion that is a non-rhinorrhea mucus secretion at a location inferior to the nose of the patient to treat a condition having a duration less the longevity of the effect of the administration of the botulinum toxin. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

Conclusion

In conclusion, applicant has shown that the present claims are not subject to estoppel under 37 CFR 1.658(c), and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 1-19 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 2/21/05

Respectfully submitted,

Frank J. Uxa
Registration No. 25,612
4 Venture, Suite 300
Irvine, California 92618
(949) 450-1750
(949) 450-1764 Facsimile